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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,470	11/02/2005	Roger R. Dzwonczyk	OSU2949PCTUS	4111

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EXAMINER	
STOUT, MICHAEL C	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
04/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/555,470	DZWONCZYK ET AL.	
	Examiner	Art Unit	
	MICHAEL C. STOUT	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *3-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Action is in response to a Response to First Action filed 6/5/2008, the remarks and declaration submitted on 12/19/2008 are being considered.

Claims 1-9 are currently pending. Claims 3-9 being withdrawn.

Affidavit/Declaration

1. The Declaration under 37 CFR 1.132 filed 12/19/2008 is insufficient to overcome the rejection of claims 1 and 2 based upon Olson et al. (US 6,731,978 B2) in view of R Dzwonczyk et al. "Myocardial Electrical Impedance Response to Ischemia and Reperfusion in Humans," R Dzwonczyk et al. Computers in Cardiology 2002; 29:541-543 as set forth in the last Office action because: The declarative statement only refers to the discloses invention and fails to make reference to the claimed invention of the currently application.

2. Furthermore, the present application lists Roger Dzwonczyk, Carlos Del Rio, Michael Howie and Patrick Connell. The cited reference while comprises only three of the inventors of the current application Roger Dzwonczyk, Carlos Del Rio, Michael Howies. Therefore even if the other contributors to the R. Dzwonczyk et al. article above are were not contributors to the claimed invention, the present application and the cited reference consist of two different inventive entities. The above article by R Dzwonczyk et al. is prior art until the applicant clarifies what Patrick Connell contributed to the disclosed and claimed invention in the instant application.

3. A similar situation provides the prior art cited in the conclusion statement: "Use of Myocardial Electrical Impedance to Assess the Efficacy of Preconditioning," CL del Rio et al. Computers in Cardiology 2002; 29:489-492, to be available as prior art for the instant application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 and 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Olson et al. (US 6,731,978 B2) in view of R Dzwonczyk et al. "Myocardial Electrical Impedance Response to Ischemia and Reperfusion in Humans," R Dzwonczyk et al. Computers in Cardiology 2002; 29:541-543.

Olson discloses the concept of a method for detecting a quantitative measure of a pathophysioloci state of a human myocardium or coronary artery of an individual (see Abstract) comprising attaching electrodes to the myocardium (electrodes 24 and 26), by recording a baseline (predetermined number of intervals Col 15, Lines 24-47) determining a varinace of the baseline values (co-variance, see Col 15 Lines 24-47) which are compared to a threshold to determine/diagnose if an adverse event has occurred. Olson fails to disclose a method for detecting a quantitative measure of a pathophysioloci state of a human myocardium or coronary artery of an individual comprising b) recording baseline measurements of the mean myocardial electrical impedance and computing the variance of the myocardial electrical impedance between each electrode pair; c) computing a baseline value of mean myocardial electrical impedance from the baseline measurements; d) periodically measuring mean myocardial electrical impedance values between each electrode pair over an interval of time and storing data representing the impedance values as a function of time; and e)

after the mean myocardial electrical impedance changes from the computed baseline value by at least the measured variance, diagnosing the extent of change in the myocardial physiologic state as a continuous, smooth, function of the extent of change, or rate of change, of the periodically measured myocardial electrical impedance from the baseline value. Dzwonczyk teaches a method of determining a pathophysiological state of an individual comprising recording baseline measurements of the mean myocardial electrical impedance (MEI is measured at 3s intervals see Section 2 Materials and Methods Paragraph 1); computing a baseline value of mean myocardial electrical impedance from the baseline measurements (see Figure 1 and Section 2 Materials and Methods Paragraph 3); periodically measuring mean myocardial electrical impedance values between each electrode pair over an interval of time and storing data representing the impedance values as a function of time (see Figure 1 and Section 2 Materials and Methods Paragraph 2) and diagnosing the extent of change in the myocardial physiologic state as a continuous, smooth, function of the extent of change, or rate of change, of the periodically measured myocardial electrical impedance from the baseline value (best shown in Figure 2). Olson and Dzwonczyk teach methods of monitoring the heart. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method disclose by Olson to include monitoring the change from baseline impedance as taught by Dzwonczyk in order to provide a reliable clinical indicator of ischemia and reperfusion in humans. Olson/Dzwonczyk fails to expressly teach the method wherein the event threshold is the combination of the mean measurement values plus the variance of the

measurement values such that after the mean myocardial electrical impedance changes from the computed baseline value by at least the measured variance. McMorrow teaches a method for determining a disease state wherein the threshold is set for each user, wherein the threshold equal to the mean (mean baseline value) plus 2.5 times the variance. Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught Olson/Dzwonczyk to include determining the event threshold by determining the mean and variance, in order to provide a threshold which is correlated to the probability that an event of interest has occurred. Olson/Dzwonczyk/McMorrow teaches the main inventive concept of selecting a threshold as a function of mean plus variance. However McMorrow fails to explicly state where the threshold is set as the mean plus the variance. At the time of the invention it would have been obvious to a person having ordinary skill in the art to set the threshold equal to the mean plus the variance with the predictable result of performing diagnosis on data representative of a proportionally high number true positive indicators of a random event by having a threshold which is set such that measurements exceeding the threshold have a higher probability of being indicators of the adverse condition, thereby not performing analysis on data which is representative of normal values, because the variance is an indication of the general distribution of the set of values used to calculate the mean, and values not exceeding the mean have a relatively higher probability of not signifying an event.

Regarding claim 2, Olson/Dzwonczyk/McMorrow teaches the method wherein: a) the physiologic state is the extent of ischemia of a portion of the myocardium (see

Dzwonczyk Abstract and Discussion); and b) after the mean myocardial electrical impedance between the electrode pairs rises above a value equal to the arithmetic sum of the baseline myocardial electrical impedance and the variance (see Discussion of claim 1 above), myocardial ischemia severity is diagnosed as a continuous, smooth, increasing function of the extent of the rise of the mean myocardial electrical impedance above the baseline value (see Dzwonczyk Figures 1 and 2, Results and Discussion).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. "Use of Myocardial Electrical Impedance to Assess the Efficacy of Preconditioning," CL del Rio et al. Computers in Cardiology 2002; 29:489-492.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

The Applicant's remarks are directed towards the Declaration filed 12/19/2008, are not persuasive. The Declaration has been found to be defective. Furthermore, even if the claimed invention is addressed in the declaration, the non-patent literature reference cited in the above office action are still available as prior art, as the references and the instant application cite different inventive entities, pending clarification from the applicant, see Affidavit/Declaration remarks above.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736